

**REMARKS**

This Amendment responds to the final Office Action mailed 21 April 2009. Claims 1, 28 and 45-48 are amended. Support for the amendments can be found variously throughout the specification and figures. No new matter has been added. Accordingly, claims 1, 4, 5, 7, 12-16, 20-22, 24, 25, 28, 33-39, 45-49, 51-54 and 57-60 are presently pending in the application, each of which Applicants believe is in condition for allowance.

**Claim Rejections – 35 U.S.C. §103**

Claims 1, 13-16, 20-21, 28, 45-49, 51-54 and 57-60 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,626,918 to Ginn et al. Applicants respectfully traverse this rejection.

Independent claims 1, 28 and 48 as amended recite “a first distal hole located in the distal end of the dilator such that the first distal hole is positionable distally beyond the distal end of the insertion sheath, the first distal hole being open for fluid flow only after being positioned distally beyond the distal end of the insertion sheath.” Independent claims 45 and 46 as amended recite “the dilator having a distal end positionable distally beyond a distal end of the insertion sheath, wherein the first distal hole is located in the distal end of the dilator; . . . wherein the first distal hole is open for fluid flow only after being positioned distally beyond the distal end of the insertion sheath.” Independent claim 47 as amended recites “a first inlet port located in the distal end of the dilator such that the first inlet port is positionable distally beyond the distal end of the insertion sheath, the first inlet port being open for fluid flow only after being positioned distally beyond the distal end of the insertion sheath.”

Ginn fails to disclose or suggest every limitation of claims 1, 28 and 45-48. Ginn discloses an obturator 214 having holes 249, 253 (*see FIGS. 10 and 11 of Ginn*) that are positionable only proximally relative to the distal end of the sheath 212 in order for all features of the Ginn device to operate as intended. The Examiner contends that although “Ginn fails to disclose that the first distal hole is located on the portion of the dilator that extends beyond the insertion sheath, . . . it would be obvious to one of ordinary skill in the art to modify the first distal hole so that it was on the portion of the dilator [obturator 214] that extends beyond the insertion sheath [212].” Applicants respectfully disagree.

First, there is no disclosure or suggestion by Ginn that the obturator 214 is a dilator or provides a dilating function. The obturator 214 includes a pigtail 233 at a distal end 232 to facilitate atraumatic advancement of the Ginn device into a blood vessel. Only the pigtail 233 extends distally beyond a distal end of the sheath 212. There is no disclosure or suggestion by Ginn that the pigtail 233 of the obturator 214 provides any dilating function, as this feature is exclusively operable to promote advancement of the device into a vessel, not dilation of the vessel. Although the following arguments distinguish the obturator 214, Applicants do not concede that it is permissible to compare the obturator 214 to the claimed dilator.

Further, Ginn goes into great detail explaining the need for two side ports 242, 250 in the sheath 212. The side ports 242, 250 are positioned proximal of a distal end of the sheath 212. Each of the side ports 242, 250 must be aligned with corresponding side ports 249, 253 defined in the obturator 214. The obturator 214 further defines a pair of channels 248, 252 that are in fluid communication with the side ports 249, 253, respectively, to provide a flow path for blood to travel to proximal openings 247, 251, respectively. If one or the other of the side ports 249,

253 is moved to a location distal of the distal end of the sheath 212, one of the side ports 242, 250 would be rendered useless and inoperative for its intended purpose of permitting blood flow into the insertion sheath 212. Thus, Ginn clearly requires alignment of the sets of side ports 242, 250 with the side ports 249, 253 at a location along the length of the insertion sheath 212 (proximal of a distal end of the sheath 212). Any other reading or interpretation of Ginn would be impermissible. Therefore, Ginn fails to disclose or suggest ports of a dilator positioned distal of a distal end of the insertion sheath, as required by claims 1, 28, and 45-48.

Still further, Ginn teaches that the side ports 249, 250 are both arranged for fluid flow (via side ports 242, 250) when at positions spaced proximal of a distal end of the sheath 212. In fact, this arrangement of the side ports 249, 250 is the only arrangement disclosed or suggested by Ginn for fluid flow in the side ports 249, 250. Thus, Ginn fails to disclose or suggest “the first distal hole being open for fluid flow only after being positioned distally beyond the distal end of the insertion sheath” (claims 1, 28 and 48), “the first distal hole is open for fluid flow only after being positioned distally beyond the distal end of the insertion sheath” (claims 45 and 46), or “the first inlet port being open for fluid flow only after being positioned distally beyond the distal end of the insertion sheath” (claim 47).

In view of the above, Applicants submit that Ginn fails to disclose or render obvious every limitation of claims 1, 28 and 45-48, and the claims that depend from them.

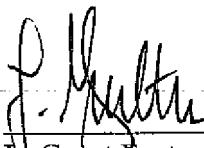
**Conclusion**

For at least the foregoing reasons, Applicants believe that each of the presently pending claims in this application is in immediate condition for allowance. Accordingly, Applicants respectfully request a favorable action on the merits. If the Examiner has any further comments or suggestions, Applicants invite the Examiner to contact the undersigned attorney to expedite the handling of this matter.

Applicants expressly disclaim all arguments, representations, and/or amendments presented or contained in any other patent or patent application, including any patents or patent applications claimed for priority purposes by the present application or any patents or patent applications that claim priority to this patent application. Moreover, all arguments, representations, and/or amendments presented or contained in the present patent application are only applicable to the present patent application and should not be considered when evaluating any other patent or patent application.

Respectfully submitted,

Dated: 22 JUNE 2009

  
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